UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| REGENERON PHARMACEUTICALS, INC.,<br><br>Plaintiff,<br><br>v.<br><br>GENENTECH, INC.,<br><br>Defendant. | Civil Action No. 10-CV-08779 (JFM) (PED)<br>ECF Case |

**GENENTECH'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION**

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## PRELIMINARY STATEMENT

As described in our opening brief, Regeneron has failed to allege either (a) that its VEGF Trap product is far enough along in its development to create a case or controversy, having not even filed for regulatory approval for the product, or (b) any affirmative act by Genentech sufficient to create subject matter jurisdiction. Regeneron's brief confirms that this Court has no jurisdiction to hear this case, and that the proper course for this Court is to dismiss Regeneron's Complaint without prejudice.

As to Genentech's first argument, Regeneron submits detail about the work it has done to prepare to commercialize VEGF Trap, and the basis for its expectations on how long FDA approval may take to receive, once Regeneron actually does file its BLA. But *Regeneron has not yet filed an application for FDA approval or otherwise engaged in activities that fall outside the safe harbor of Section 271(e)(1) or that reflect an imminent threat of infringing activities.* The posture of this case is dramatically different from every case Regeneron relies on in support of its argument.

As to Genentech's second argument, Regeneron responds that it has sufficiently pleaded an affirmative act by Genentech simply by alleging, on information and belief, that "Genentech has indicated, among other things, that Regeneron's VEGF Trap will not have freedom to operate based on the Davis-Smyth Patents and referred to Regeneron's discussion of the threat of the Davis-Smyth Patents in its SEC filings." (Compl. ¶ 17.) Regeneron now asserts for the first time that it was Genentech's Chairman, Dr. Arthur Levinson, who supposedly made these statements, and that he made them to two Regeneron investors (whose identity Regeneron wishes to shield from disclosure). (Compl. ¶ 17; Opp'n Br. at 10-12.) Tellingly, these assertions are not set forth in Regeneron's Complaint. Nor are they made (or substantiated) in any of the numerous declarations Regeneron submitted in opposition to Genentech's motion. Instead, they

appear only as lawyer argument in Regeneron's opposition brief, which is insufficient as a matter of law to save a complaint from a motion to dismiss. Dr. Levinson also denies ever making any such statement. But even if Regeneron could properly plead that Levinson said that Regeneron's VEGF Trap would not have freedom to operate (which Regeneron did not do), and even if Levinson made these statements (which he did not), there would *still* be no ripe controversy. Regeneron has identified no case holding that a one-off statement baited by a potential infringer's investor, like the one it now accuses Levinson of making, is a sufficient "affirmative act" to create a ripe controversy.

For all the reasons set forth below and in Genentech's opening brief, this case is not yet ripe, and we respectfully submit that this Court should dismiss the Complaint without prejudice.

**ADDITIONAL STATEMENT OF FACTS**

In response to Regeneron's newly-asserted claims that Dr. Levinson purportedly made statements to investors about Regeneron's freedom to operate, Dr. Levinson has submitted a declaration, denying that he ever said to Regeneron or its investors that Regeneron lacked freedom to operate vis-à-vis its VEGF Trap. (Levinson Decl. ¶ 2.)

First and foremost, Dr. Levinson does not even recall having discussions with the investors identified by Regeneron about Genentech's intellectual property in connection with Regeneron's VEGF Trap. Moreover, had any such discussion occurred, it would necessarily have occurred years ago (before March 2009). And to the extent the topic of the interplay between Genentech's intellectual property and Regeneron's VEGF Trap product may have come up, it would only have been in response to a specific question, and it was Dr. Levinson's practice to limit his remarks to directing investors to Regeneron's own statements regarding risks related to intellectual property and their acknowledgement of Genentech's patents. (Levinson

Decl. ¶ 5.) Such conduct hardly qualifies as an immediate threat of suit and does not suffice under the case law to create jurisdiction.

## ARGUMENT

### I.

### THERE IS NO JUSTICIABLE CONTROVERSY HERE BECAUSE REGENERON HAS NOT SOUGHT REGULATORY APPROVAL TO COMMERCIALIZE VEGF TRAP

In our opening brief (at 11 to 14), we showed that there is no controversy here "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Significantly, Regeneron has not yet sought regulatory approval from the FDA to commercialize VEGF Trap and has not otherwise engaged in activities that could qualify as acts of infringement or reflect an imminency to engage in such acts. *See MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007). In response, Regeneron cites cases where the facts were found to constitute a ripe controversy. Those cases confirm only what is missing here:

**An Application for Regulatory Approval:** Regeneron's Complaint conceded that Regeneron had not sought a Biologics License Application from the FDA. (Compl. ¶ 11.) Regeneron admits this again in its brief. (Opp'n Br. at 2.) And while Regeneron provides information about the steps it has purportedly taken to increase the likelihood that its BLA, if filed, will be granted quickly, the fact remains that *it is not on file*.

The absence of a filed BLA distinguishes many of the cases on which Regeneron relies. In *Infinitech, Inc.* v. *Vitrophage, Inc.*, the potential infringer had already filed its application for FDA approval. *See* 842 F. Supp. 332, 334 (N.D. Ill. 1994). Indeed, in that case the defendant patentee cited the plaintiff's application to the FDA as an act of infringement. *Id.* Similarly, in *Amgen, Inc.* v. *F. Hoffman-LaRoche Ltd.*, potential infringer Roche had also filed a BLA with the FDA. *See* 456 F. Supp. 2d 267, 271 n.1 (D. Mass 2006).

**Conduct Outside the Section 271(e)(1) Safe Harbor:** The *Amgen* case Regeneron cites is also inapposite because the patentee-plaintiff alleged that Roche was engaging in infringing acts outside of the safe harbor of Section 271(e)(1). *See id.* at 274. Regeneron has not alleged that it has engaged in any such acts here.

Regeneron suggests this does not matter, arguing that *Biogen, Inc.* v. *Schering AG* teaches that even activities within the safe harbor can support a declaratory judgment action. 954 F. Supp. 391 (D. Mass. 1996). Regeneron misreads *Biogen*, which actually supports Genentech's position, not Regeneron's. Biogen, like Regeneron, sought a declaratory judgment of non-infringement. Schering, the patentee, argued that the case was not ripe, because all of Biogen's activities – like those alleged by Regeneron – fell within the safe harbor of Section 271(e)(1). The court never ruled, as Regeneron would have this Court believe, that safe-harbor-protected conduct can support a declaratory judgment action. Instead, the court found that Biogen had engaged in conduct *outside* the safe harbor, and on that basis held that the lawsuit was ripe:

> Biogen had done far more than merely do clinical trials for submission to the FDA, it had spent $24 million to stockpile and prepare to market Avonex immediately upon the anticipated, imminent FDA approval in order to access promptly the lucrative market for beta interferon drugs to combat multiple sclerosis. *These actions took Biogen out of the "safe harbor," made it subject to suit as of May 3, 1996, and gave it standing to sue itself.*

954 F. Supp. at 396-97 (emphasis added).

Regeneron now asserts that it has made a significant investment, both in terms of money and staffing, to prepare for the future commercialization of VEGF Trap. None of these assertions, however, establish that Regeneron has engaged in conduct, at the time the Complaint was filed, that could be considered an act of infringement or to make a putative act imminent –

least of all in a way keeping with the facts of *Biogen*. *See id*. Indeed, the *Biogen* suit had been filed *more than a year* after Biogen had submitted to the FDA its Product License Application (and *two weeks before it was granted*); the court found commercialization activities there sufficient to establish jurisdiction because, post-FDA filing, Biogen had actually produced and stockpiled the commercial version of its drug in anticipation of receiving the FDA's approval and there was an imminent threat of putative infringement. *See id.* There is nothing comparable here. *See also Arrowhead Indus. Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731, 739 (Fed. Cir. 1988) (Arrowhead was in a position to offer its services to customers and, hence, immediately engage in allegedly infringing activities).[1]

Because Regeneron's Complaint does not establish that it had undertaken any acts to commercialize VEGF Trap that could support a patent infringement claim at the time the Complaint was filed, this case is not justiciable as a matter of law.

**II.**

**THERE IS NO JUSTICIABLE CONTROVERSY HERE BECAUSE REGENERON HAS NOT ALLEGED ANY AFFIRMATIVE ACT BY GENENTECH**

In our opening brief, we showed that, in all the post-*MedImmune* declaratory judgment cases finding a case or controversy, there had been "some affirmative act by the patentee." *SanDisk Corp.* v. *STMicroelectronics Inc.*, 480 F. 3d 1372, 1381 (Fed. Cir. 2007) (*see generally* Opening Br. at 14-17). Regeneron's Complaint failed to allege such an affirmative act, instead making only veiled reference to conduct by Genentech: "Regeneron is informed and believes, and thereon alleges, that Genentech has indicated, among other things, that

[1] Regeneron also asserts that it will make additional investments in the future in VEGF Trap. (*See* Terifay Decl. at ¶ 4.) Assertions about what Regeneron may do or intends to do in 2011, however, cannot shore up a Complaint filed in November 2010. The "presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed." *Arrowhead Indus.*, 846 F.2d at 734 n.2.

Regeneron's VEGF Trap will not have freedom to operate based on the Davis-Smyth Patents and referred to Regeneron's discussion of the threat of the Davis-Smyth Patents in its SEC filings." (Compl. ¶ 17.) Regeneron did not allege who at Genentech so "indicated," to whom they so "indicated," or what the unspecified "other things" are. (Regeneron's choice of the phrase "its SEC filings" cannot hide the fact that they were Regeneron's filings, not Genentech's.)

In its opposition brief (at 11 to 12), Regeneron asserts for the first time that it was Genentech's Chairman Arthur Levinson who purportedly made these statements, and that he made them to two of Regeneron's investors. But Regeneron's papers themselves reflect that Regeneron has not supported this charge; these details are only attorney argument. *See, e.g.*, *Loveman* v. *Lauder*, 484 F. Supp. 2d 259, 267 (S.D.N.Y. 2007) (dismissing complaint where, among other things, particularized facts required did not "appear in the complaint [and] are simply lawyers' arguments"). Not a single one of Regeneron's declarants testifies to Levinson's supposed statements. Regeneron's opposition ultimately leaves the Court where it began – with a Complaint that contains a vague allegation made on information and belief, with absolutely no evidentiary support.[2]

**Regeneron's Allegations Are Inadequate:** Regeneron's failure in pleading alone should end the question. Its Complaint is silent on details surrounding these alleged statements, and even in its opposition, Regeneron has provided no evidentiary support

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[2] Regeneron seeks to estop Genentech from denying that Levinson made these statements, because Genentech did not do so in its opening brief. This argument has no merit. The reason that Genentech did not do so in its opening brief is that Regeneron *had not sufficiently put Genentech on notice* that the allegations referred to statements allegedly made by Dr. Levinson until Regeneron filed its opposition brief. The prohibition on raising arguments in reply applies to only arguments that could have been anticipated.

In the alternative, Regeneron asks to take discovery about other, hypothesized statements not even alleged in the Complaint. For the reasons discussed in the body of this brief, below, this request should also be denied.

whatsoever for its assertions regarding who made what statements to whom regarding Regeneron's freedom to operate. Regeneron has failed to carry its burden to demonstrate the existence of jurisdiction.

**Dr. Levinson's Statements Do Not Support Jurisdiction:** The Genentech statements that Regeneron alleges constitute an affirmative act appear to comprise two parts: Genentech purportedly (a) stated that VEGF Trap will not have freedom to operate based on the Davis-Smyth Patents and (b) referred to Regeneron's discussion of the Davis-Smyth Patents in Regeneron's SEC filings. Regeneron in its brief now specifically attributes both of these statements to Dr. Levinson. Even this lawyer argument still does not identify when or where the statements were allegedly made, or under what circumstances. In fact, the only evidence before this Court as to what Dr. Levinson may have said is offered by Dr. Levinson in his declaration.

As to the first part, Dr. Levinson attests that he never stated that VEGF Trap will not have freedom to operate based on the Davis-Smyth Patents – either to the investors Regeneron identifies or to any other. (Levinson Decl. ¶ 2.) As to the second part, Dr. Levinson has stated that *any* statements he made about Regeneron to investors would only have been made years ago, and would only have been made in response to a specific question. He also has stated that it was his consistent practice, if asked about Regeneron's VEGF Trap product, to refer the questioner to Regeneron's own long-standing disclosures on the subject. This does not constitute an affirmative act by Genentech creating an immediate controversy. Indeed, the only affirmative act that has been established is that Regeneron itself raised, in its securities filings, the risk that it would infringe Genentech's patents. However, Regeneron's own affirmative acts cannot alone create a reasonable apprehension of suit. *See, e.g., Innovative Therapies, Inc.* v. *Kinetic Concepts, Inc.*, 599 F.3d 1377, 1381-82 (Fed. Cir. 2010).

Even if (counterfactually) Dr. Levinson had gone an extra step and made a representation about Regeneron's freedom to operate, as Regeneron now asserts, that would still be insufficient to establish subject matter jurisdiction. Regeneron points to no case in which old, isolated, solicited statements, made to someone other than the proposed infringer or its customer, sufficed to create jurisdiction. That no case permits such an attenuated basis for establishing jurisdiction is not surprising. As noted in our opening brief, courts have found there to be no justiciable controversy even where deliberate statements are made directly to the infringer. For instance, in *Geospan Corp.* v. *Pictometry Int'l Corp.*, the court found no justiciable controversy even though the patentee sent to the alleged infringer a letter identifying the patent, stating that infringer's products "'may incorporate the technology covered by this patent,'" and attaching a claim construction order from a case in which the patentee sued to enforce its rights. 598 F. Supp. 2d 968, 969 (D. Minn. 2008).[3] There was still no sufficient affirmative act because, as here, the patentee "ha[d] not demonstrated an intent to litigate against [the alleged infringer], ha[d] not accused [the alleged infringer] of infringement, and ha[d] not demanded licensing fees." *Id.* at 971.

[3] While "*MedImmune* may have lowered the bar for determining declaratory judgment jurisdiction," a "lowered bar does not mean no bar at all. Indeed, a declaratory judgment plaintiff must show that the dispute is 'definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Hewlett-Packard Co.* v. *Acceleron LLC*, 587 F.3d 1358, 1361-62 (Fed Cir. 2009) (quoting *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007)); *see also Hewlett-Packard*, 587 F.3d at 1362 (explaining that "a communication from a patent owner to another party, merely identifying its patent and the other party's product line, without more, cannot establish adverse legal interests between the parties, let alone the existence of a 'definite and concrete' dispute. More is required to establish declaratory judgment jurisdiction.").

Contrary to Regeneron's representations, *West Interactive Corp.* v. *First Data Res., Inc.*, 972 F.2d 1295 (Fed. Cir. 1992), did not hold that there is "no requirement that statements must be made directly to the declaratory judgment plaintiff." (Opp'n Br. at 12.) That point was made by the dissent. *See id.* at 1299 (Lourie, J., dissenting). Similarly, *Biogen, Inc.* v. *Schering AG*, 954 F. Supp. 391 (D. Mass. 1996), did not, as Regeneron implies, hold that statements to the media might suffice to demonstrate the existence of an actual controversy. (*See* Opp'n Br. at 12.) There, the court found an actual controversy based on a *number* of affirmative acts, including Schering's direct assertion to Biogen that the exportation of Biogen's product "would infringe Schering AG's '567 Patent and, therefore, could if necessary be prevented." *Id.* at 394.

Regeneron's repeated references to the Federal Circuit's decision in *Arrowhead Industrial Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731 (Fed. Cir. 1988) – and its disapproval of patent owners who engage in "[g]uerrilla-like" tactics and "brandish[] a Damoclean threat with a sheathed sword" – are equally unavailing. *Id.* at 735; *see* Opp'n Br. at 12. That case, if anything, serves to illustrate the *gap* between the allegations here and what would suffice to demonstrate an actual controversy. Arrowhead was in a position to offer the infringing services to customers in direct competition with Ecolochem. Moreover, Ecolochem had direct communications with Arrowhead in which it effectively accused Arrowhead of infringement. Ecolochem had sent a letter to Arrowhead enclosing its patent, claiming that "'Arrowhead is contemplating or has initiated the practice of the patented process,'" and demanding that Arrowhead discontinue any "'unauthorized' practice." *Arrowhead Indus.*, 846 F.2d at 733. The court observed that the only act that Ecolochem did not take was to use the word "infringement" in a direct communication with Arrowhead. *See id.* at 737. Those facts are entirely absent here.

To the extent that the alleged statements at issue would have been made in response to questions from Regeneron investors, that also counsels against finding a justiciable controversy. "A patentee has no obligation to spend the time and money . . . to make a definitive determination, at the time and place of the competitors' choosing, that it will never bring an infringement suit." *Prasco, LLC* v. *Medicis Pharm. Corp.*, 537 F.3d 1329, 1341 (Fed. Cir. 2008) (holding patentee's decision not to sign a covenant not to sue insufficient to create an actual controversy). It is one thing to require a patentee that takes an affirmative step to deal with the resulting burden of a lawsuit seeking a declaration of the target's rights. It is quite another for a potential infringer to manufacture jurisdiction by seeking to create a controversy where none exists. *See, e.g., Innovative Therapies, Inc.*, 599 F.3d at 1381 (court found patentee's employees' "informal conversations" instigated "sub rosa" by potential infringer who, patentee argued, sought "indirect evidence of a controversy without subjecting itself to the possibility of suit" "did not produce a controversy of such 'immediacy and reality'" to confer subject matter jurisdiction).

**Genentech's Post-Suit Actions Do Not – and Cannot – Support Jurisdiction:** Regeneron also improperly asks this Court to consider conduct that occurred since the time that Regeneron filed suit, claiming that it somehow "confirms" the controversy between the parties. (Opp'n Br. at 13.) Specifically, Regeneron claims that this Court should consider Genentech's decision not to provide a covenant not to sue to Regeneron. (Opp'n Br. at 13.)

Conveniently, Regeneron did not mention in its papers that it requested such a covenant only *after* Regeneron filed this lawsuit against Genentech. (*See* Genentech's January 27, 2011 Letter, Naini Decl. Ex. B ("Your letter came as somewhat of a surprise given Regeneron's decision to file a lawsuit against Genentech in November without making any effort

to contact us in advance.").) Because jurisdiction is determined as of the time of the filing of the complaint, courts have rejected arguments that post-complaint acts can retroactively support jurisdiction.

In *Innovative Therapies, Inc.* v. *Kinetic Concepts, Inc.*, 599 F.3d 1377 (Fed. Cir. 2010), for example, the Federal Circuit found Kinetic Concepts's later-filed affirmative infringement suit against Innovative Therapies irrelevant to whether Innovative Therapies' earlier-filed declaratory judgment action was justiciable. *Id.* at 1383-84. As the district court explained, "to hold otherwise 'would invite a declaratory judgment plaintiff in a patent case to file suit at the earliest moment it conceives of any potential benefit to doing so, confident that it will either draw an infringement suit in response (thereby retroactively establishing jurisdiction over their first-filed declaratory judgment suit) or will suffer no adverse consequence other than having its suit dismissed.'" *Id.* at 1384 (quotations omitted). So too here. Regeneron should not be permitted to rely on its post-Complaint efforts to manufacture a controversy to establish jurisdiction.

**Regeneron Is Not Entitled to a Fishing Expedition:** This Court should also reject Regeneron's last-ditch argument that, if all else fails, it should be permitted discovery as to what *other* Genentech executives *may* have said to *other* investors. (Opp'n Br. at 24.) "In a declaratory judgment action, the complaint must stand or fall on its own merits and cannot be used as a vehicle for searching out and discovering a right of action." *Fifth Ave. Peace Parade Committee* v. *Gray*, 480 F.2d 326, 333 (2d Cir. 1973) (internal quotation omitted). It was "incumbent upon" Regeneron to "allege a 'justiciable controversy' in order to state a claim for declaratory relief." Charles Alan Wright & Arthur R. Miller, 5 Federal Practice & Procedure (Civil) § 1238 (3d ed. 2006). Regeneron plainly failed to do so.

Moreover, none of the cases Regeneron cites supports a right to the discovery it now requests. In fact, all but one are inapposite in that they concern *personal jurisdiction* and the defendant's contacts with the forum. The other, *APWU* v. *Potter*, 343 F.3d 619 (2d Cir. 2003), actually affirmed the *denial* of additional discovery. *Id.* at 627.

"The burden is on the party claiming declaratory judgment jurisdiction to establish that such jurisdiction existed at the time the claim for declaratory relief was filed and that it has continued since." *Benitec Australia, Ltd.* v. *Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007). Regeneron has failed to meet this burden.

## CONCLUSION

For the foregoing reasons, Genentech respectfully requests that this Court dismiss Regeneron's Complaint for lack of subject matter jurisdiction.

Dated: February 22, 2011
Washington, D.C.

Respectfully submitted,

*/s/ Craig A. Benson*

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